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EXAMINER

DAVIS, DEBORAH A

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/08/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/638,102

Applicant(s)

SCHWARTZ, DAVID C.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5-21 and 23-36 is/are pending in the application.
- 4a) Of the above claim(s) 14-21,23-33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 35 is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,9-13,34 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicants' response to the office Action mailed on June 3, 2003 in Paper No. 18 has been acknowledged. Currently, claims 1-2, 5-13, 34-36 are pending. Claims 14-33 are withdrawn. Claims 2 and 4 have been cancelled.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 6, 7, 9, 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al (USP# 4,867,946) in view of Stuelpnagel et al (USP#6,396,995).

Gross et al anticipates the instant claims by teaching a device for evaluating test strips used to screen a variety of different samples. The test strips contain several test sections where the reagents are placed for testing (col. 1, 2<sup>nd</sup> para and see Figure 2). The device has a platform and a holder to support the test strips (col. 2, see claim 1) in a parallel relationship in which the test strips are perpendicular to the holder (see Figure 2). The test strip has test sections spaced along the strips to allow samples to be deposited (see Figure 2). The limitation "support frame holding the plurality of different filaments for mutual exposure to a material to be screened" as recited in claims 1, 34, and 36 will not be given patentable weight because it is intended use. With respect to

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the recitation of a "semi-custom array for chemical screening" in the preamble has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951).

Gross et al differ in the instant invention because it does not specifically point out that the organic compounds used are from the groups of oligonucleotides and peptides and that the substrate is of glass fiber.

Stuelpnagel et al teaches an optical imaging system that contains an array of multiple fiber optic bundle strips (see figure in abstract). In the detailed description of the preferred embodiments, a variety of bioactive agents are used in this optical system (col. 12, lines 26-32) such as oligonucleotides, polypeptides, proteins etc. (col. 11 paras. 4 and 5) and substrates, such as glass, are used and well known in the art (col. 8, lines 45-50). A variety of bioactive agents are used to provide a sufficient range of binding to target analytes (col. 12, lines 26-32).

It would have been obvious to one of ordinary skill in the art to incorporate a variety of bioactive agents of Stuelpnagel et al in the screening device of Gross et al to have a sufficient range of binding to target analytes.

4. Claims 5, 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Bensten et al (USP#6,372,895).

The teachings of Gross et al are set forth above and differ in the instant invention because it does not teach strips that include a marker selected from the group of printing and fluorescent material nor the use of organic compounds.

However, Bentsen et al teaches in one of his embodiments an apparatus that uses a test strip that contains a printed barcode wherein the printed material on the barcode has an enzyme or spore. The strip is further sterilized and dipped into a buffer solution containing Fluorescence Enzyme Substrate (FES). If enzyme activity is present, the printed pattern will become detectable (col. 20, lines 66-67 and col. 21, 1<sup>st</sup> para).

It would have been obvious to one of ordinary skill in the art to have incorporate the printed barcode as taught by Bentsen et al into the strips of Gross et al to detect enzyme activity. With respect to claim 5, "wherein the non-reactive strip is a glass fiber" constitute an obvious variation in design that is routinely modified in the art and which have not been described as critical to the practice of the invention, especially since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. In re Stevens, 101 USPQ 284 (CCPA 1954).

### ***Response to Arguments***

5. Applicant's arguments with respect to the Gross et al rejection have been considered but are moot in view of the new ground(s) of rejection.
6. Applicant's arguments with respect to the Gross et al in view of Stupenagel et al have been considered but they are not found persuasive. Applicant's argument that

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Stuelpnagel et al teaches away from putting reactive substances along the length of the fiber by expressly teaching that the reactions are detected using light conducted from microspheres through one end of the fiber and that the sides of the fiber are coated with wax or other registration material is not found persuasive. The Stuelpnagel et al reference was relied upon to teach solid phase coating of oligonucleotides and peptides on fibers. The primary reference of Gross et al already teaches a plurality of reagents such as proteins, bilirubin and various other reagents along the length of strips (fibers). One would be motivated to modify the Gross et al reference to include oligonucleotides and peptides along with other reagents to screen for potential binding partners for target analytes (See Stuelpnagel et al, col. 12, lines 26-32). Absent evidence to the contrary, the coating of reactants in various or diverse configurations (a long the length of the strip, at the end, etc.) appear to be mere optimization of the device taught by the prior art. Therefore, it is the Examiner's position that the Gross et al in view of Stuelpnagel are obvious over applicant's invention.

### ***Conclusion***

#### ***Allowable Subject Matter***

7. Claims 8 and 35 are allowed.

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8. The following is a statement of reasons for the indication of allowable subject matter: The prior art neither teaches nor suggest that filaments or strips in the instant claims include isolating bands of chemically repellant coating between the chemically reactive substances.

9. Claims 8 and 35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123



Deborah A. Davis  
CM1, 7D16  
August 27, 2003



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09/05/03